

Guidance and Procedure: Recruitment and Screening Methods and Materials (last updated September 28, 2012)

[Introduction](#)

[Ethical Concerns](#)

[Principles for Using Records to Identify Prospective Subjects](#)

[Acceptable Recruitment Methods](#)

[Unacceptable Recruitment Methods](#)

[Who May Recruit](#)

[Family Member Recruitment](#)

[Employee and/or Student Recruitment](#)

[Recruitment Materials](#)

- [Materials Requiring IRB Review](#)
- [Advertisement Requirements](#)
- [Limitations to Recruitment Materials and Posting at Other Sites](#)

[Screening Activities](#)

[Regulations and References](#)

Introduction

Identification, initial contact, screening and recruitment of potential human subjects form the foundation of the informed consent process. The research team, the study sponsor, and the IRB share the responsibility for creating a recruitment environment that is not only effective but is also ethical and that complies with the federal regulations and guidance. These responsibilities require consideration of the appropriate procedures for the initial identification, contact, screening and recruitment of potential subjects. Both the screening and the recruitment process should demonstrate and reflect respect for the dignity and autonomy of the potential participants by avoiding any potential undue influence and by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment and/or screening purposes.

Ethical Concerns

The research team and the IRB will need to consider the following ethical questions when evaluating recruitment strategies:

- **Equitable selection of participants:** Does the recruitment strategy help ensure that selection of research participants is equitable and appropriate for the study?
- **Respect for privacy:** Does the recruitment strategy respect an individual's reasonable expectations for privacy? If the research team asks questions for screening will the questions be asked in a private setting where others will not overhear the answers? Will patients who are recruited from a recruitment database in the clinic have given their permission beforehand for this use of their medical information?
- **Lack of pressure:** Is the study introduced in a way that allows subjects ample time to consider, with no undue pressure because of timing of the request, **who** makes the request, **how** the

request is made, or the offering of excessive inducements? Will students be hesitant to say “no” to a professor? Will patients be put in a situation where they may hesitate to say “no” to their own physician? Will adolescents whose parents give permission for them to be in a study feel they cannot now say “no”? How will pressure be minimized?

- **Unbiased presentation:** Is all information accurate, balanced, and free of misleading emphases that make the study excessively attractive? Is the information as complete as is appropriate for each stage of recruitment?
- **The “Therapeutic Misconception:”** Patients tend to believe a clinical trial—or anything proposed by health care providers—will benefit them, even if they’re told there is no assured benefit. Does the recruitment strategy work to counteract this misconception?
- **Conflicting concerns:**
 - Students may feel obliged to participate in a researcher’s study if that researcher is also their professor.
 - Prospective participants may prefer that someone involved in their care contact them about research, but they may find it hard to say “no” to a care provider.
 - Clinicians may find their clinical judgment in conflict with a desire to enroll patients in their research.

Principles for Using Records to Identify Potential Subjects

- **The review of student records** for the purpose of identifying, contacting, and recruiting participants is subject to the rules set forth in the Family Educational and Rights Privacy Act (FERPA). See [OHRPP Guidance & Procedures: FERPA](#).
- **Use of medical records** for the purpose of identifying, contacting, and recruiting participants is subject to HIPAA regulations. See [OHRPP Guidance & Procedures: HIPAA](#). Access to medical records and identifiable health information by people not directly involved in a patient’s care is highly restricted.
- **Use of Protected Health Information (PHI) and Personal Identifying Information (PII):** The amount of identifiable information gathered and the number of people who have access to identifiable information must be minimized. See [OHRPP Tip Sheet](#) which describes both PHI and PII.

Acceptable Recruitment Methods

In preparing recruitment materials the researcher should consider the purpose of the research, the setting in which the research will be conducted, and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. See [Section 9: Populations](#) of OHRPP Guidance for more details about the considerations for the specific population groups.

The following methods of recruiting subjects have been used in studies being conducted at UCLA and are generally acceptable. There may, however, be extenuating circumstances in which one of the methods might not be appropriate for a particular study. This is not an exhaustive list but it is an outline of the most commonly-used methods for recruitment and includes both behavioral and biomedical recruitment strategies. One study may employ more than one method of recruitment. The method(s) of recruitment should be discussed within Section 3 the webIRB application.

- **Advertisements, flyers, information sheets, notices, internet postings and/or media are used to recruit subjects.** The text of these needs to be included within or as an attachment to the webIRB application. *The IRB must approve the text of these.* Prospective participants who respond to these will contact the study investigators.

IMPORTANT NOTES: 1) No HIPAA-regulated Protected Health Information is used in this recruitment strategy. 2) See guidance below on suggested text for ads and notices.

- **Direct recruitment of potential study participants.** Examples of this strategy are physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet. With this method considerable care will have to be taken so that the person contacted does not feel pressured to participate.
- **Recruitment letters.** Ideally the recruitment letter would come from someone or some agency or clinic known to the prospective subject informing the prospective participant about the study. Preferably, the letter would ask the person to call for additional information or if interested in participating in the study or return a post card or send an e-mail. However, there may be situations, for example for large scale low risk studies, in which it would be acceptable to ask the person to opt out if not interested or when contacted by phone or e-mail or in person. These points should be addressed in the IRB application.

The recruitment letter can be brief but it should include information about how the person was identified to be sent the letter, what is involved if the person participates and an overview of any risks or potential benefits. It should also let the person know how to inform someone if he or she wants to participate, not to participate, or where to get answers to additional questions, and, of course, who is doing the study and why.

- **Random or other probability sampling.** This could include snowball sampling, random digit dialing, or other methods used primarily in the social and behavioral sciences.
- **Referrals.** Referrals may be from non-investigator healthcare providers, snowball sampling, participants referring other participants. Investigators may provide their colleagues with a “Dear Patient” letter or a “Dear Potential Study Participant” letter describing the study. Or researchers may provide Information Sheets to colleagues or associates.

IMPORTANT NOTE: When Personal Health Information is involved, investigators who are not the health care providers or part of the clinic providing health care are prohibited from having access to patient names, addresses, phone numbers or medical record numbers. Patients must initiate contact, unless there is documented permission from the patient (i.e., note in medical record that primary care provider spoke with patient who agreed to be contacted) that the patient agreed to be contacted.

- **Participant Pool.** These are pools for which potential research participants have given permission for future contact. See OHRPP Guidance on [Student Subject Pools](#).
- **Another IRB-Approved Screening and/or Recruitment Protocol and/or Recruitment Database:** This protocol describes how potential research participants will be asked for and will give permission for future contact. Investigators contact these potential subjects about particular studies in accord with their protocol and the (typically signed) consent of the prospective subject. In many case, prospective participants may have given permission to be contacted for future studies by means of check-off box in a consent form for a previous study.
- **Review of medical records to identify potential research participants:** Study investigators request a Waiver of Consent/Authorization for recruitment purposes. In all cases the waiver must be justified in the webIRB application.

- Review of publicly available records.
- Review of other records.

Unacceptable Recruitment Methods

- **Direct Recruitment by Study Sponsors:** In general, UCLA does not permit its researchers to provide subject contact information to sponsors. Sponsors may not directly contact prospective subjects based on information from UCLA researchers. **However**, UCLA does, of course, permit a study to be part of a national or local multi-site study which may include a national or local advertising campaign by the study sponsor to recruit subjects.
- **Use of Incentives and Referral Fees:** Per-patient incentive payments or referral fees, whether paid for each referral or each enrollment, are not allowed. Such payments may encourage recruiters to put inappropriate pressure on prospective subjects and are illegal in California. Lump-sum payments not tied to the number of patients referred or enrolled may be allowed in particular studies. Investigators should include all information about incentives and/or referral fees in the recruitment section of the webIRB application.

However, in some social behavioral research minimal risks studies it is not unreasonable to offer a small token gift for referrals, for example, in snowball sampling.

- **Medical Record Access:** As stated above, when Personal Health Information is involved, investigators who are not the health care providers or part of the clinic providing health care are prohibited from having access to patient names, addresses, phone numbers or medical record numbers. Patients must initiate contact, unless there is documented permission from the patient (i.e., note in medical record that primary care provider spoke with patient who agreed to be contacted) that the patient agreed to be contacted.

Who May Recruit

Initial Contact: Prospective research subjects should be contacted by someone who is

- Thoroughly knowledgeable about the study,
- Able to answer questions,
- Trained in the voluntary nature of research participation and
- The most appropriate person to contact prospective participants.

When treatment or medical care is involved, prospective participants should be contacted by persons directly involved in their care, not by unknown researchers.

For purposes of recruitment, people are considered “involved in the patient’s care” (and therefore eligible to review HIPAA-protected information without an authorization or waiver) if they are (1) health care professionals actually involved in the care or (2) administrative or research staff working with the professionals involved in the care.

Family Member Recruitment

In cases when a family member is asked to recruit another family member or members into a study, the researcher should consider how best to protect and respect the privacy of family members who may be identified as potential participants.

One way to respect and preserve the privacy of family members is for the researcher to develop a strategy that allows the family member who is already in the study to provide information sheets that explain the study to other family members. This allows the potential participant to contact the research team to express interest.

There are other methods to protect the privacy of the family. Whatever method is used should be carefully considered and described in the IRB application.

UCLA Employee and/or Student Recruitment

If a researchers wish to enroll their own students or people they directly supervise into one of their studies, there are special provisions that need to be considered and implemented so that the students or employees do not feel obliged or pressured to participate in the study. Investigators should carefully consider the appropriateness of enrolling individuals they directly supervise or instruct and will require explicit justification in the IRB application. See [OHRPP Guidance & Procedures: Special Subject Populations–Students & Employees.](#)

If UCLA employees and/or students are asked to participate in a research study, the investigator may be asked to provide written assurance in the webIRB application and indicate in the informed consent form that willingness to enroll in the research study will in no way affect subjects' grades, employment or standing within the University.

Recruiting Researchers' Students and Staff: In order to avoid undue influence or pressure on a prospective subject, researchers should not directly ask their students or staff to be research subjects. It may be difficult to refuse such a request. Rather, researchers should post flyers or provide information sheets that allow volunteers to initiate contact about the study.

Recruitment in Classrooms: If researchers wish to recruit in the classroom, they must make it very clear that research is voluntary and will not be tied to grades or extra credit. It must be clear that there will be no stigmatization or ostracizing of students who decline to participate. If class time will be taken for research participation, alternative activities should be provided for those who decline (especially in pre-college levels).

[UCLA Center for Student Programming](#) links to all student organizations, some of which might be a source of potential volunteers. This will also link to the flyer posting service. CSP@ucla.edu can be used for inquires about appropriate posting locations.

Recruitment Materials

All recruitment materials require IRB review and approval prior to implementation. The following types of recruitment documents must be submitted as part of the initial application for IRB review. The IRB application should describe how the materials will be used. Any additions or changes to these documents must be submitted via webIRB as formal amendments to the study.

- **Letters to or Information Sheets for Subjects:** All letters to or information sheets for subjects or their representatives, regardless of who signs the letters, including the PI, a primary care provider, or an organization the subject has joined.
- **Advertisements:** The text of all advertisements in all media, including flyers, posters, newspaper ads, radio or television announcements, and informational videos. **However,** investigators are not required to submit to the IRB the final version of an advertisement as long as the template, actual text or script has been approved and does not modify what was approved. Investigators are responsible for maintaining copies of the final product in the research files.
- **Scripts:** All scripts or guides that will be used for in-person or telephone recruitment interviews.
 - If such screening activities will take place **prior to the subject providing informed consent** for participation in the research, the researcher may request a waiver of informed consent or signed informed consent for screening activities in accordance. See [OHRPP Guidance for Requesting Waivers and Exceptions to Informed Consent.](#)

- If screening activities will take place only **after the subject has provided informed consent** for participation in the research, then the waivers described above are unnecessary.
- **Web Postings or Pages:** Submit printouts of postings or pages used for direct recruitment. **However**, web site postings that are limited to basic study information, such as title, purpose of the study, basic eligibility criteria and study site location, intended for informational purposes and not solely for recruitment may not require IRB review and approval.

HIPAA regulations may apply to the screening process if it involves review of medical records. Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent. Please see *OHRPP Guidance & Procedures: HIPAA* for details.

Advertisements to recruit subjects are normally limited to the following information to determine eligibility and interest. The following elements are **suggested but not required**, though UCLA should be referenced whenever appropriate (for example, exceptions may be made for national campaigns). The information should be worded to be informative but not coercive, overly enticing or promising benefit.

- Indication that the recruitment is for a “UCLA Research Study”
- Name and address of researcher *and/or* research facility
- Indication that the recruitment is for a “UCLA Research Study”
- Condition under study or the purpose of the research
- Criteria that will be used to determine eligibility (in summary form)
- A brief list of significant risks, if any
- A brief description of benefits of participation, if any
- Payment, if any
- Time commitment required
- The location of the research
- Person or office to contact for further information
- Indication that the recruitment is for a “UCLA Research Study”
- **For clinical trials**
 - Whether or not the investigational agent is FDA-approved for the given indication
 - Indication that the study participant may receive a placebo

Limitations to recruitment materials: Researchers and the IRB must ensure that all materials used for recruitment **do not**:

- **Characterize payment as a benefit**, be the focus of the material, emphasize payment by using a larger font or bold type, or promise a bonus for completion of the study.
- State or **imply a certainty of a favorable outcome** or other benefits beyond what is outlined in the consent documents.
- **Include any exculpatory language** that appears to waive any rights of the prospective participants or indicate that the investigator or University cannot be held liable or at fault for any research-related event.
- **For clinical trials**, recruitment materials should not
 - Make any claims, either explicitly or implicitly, that the **experimental agent is known to be safe or effective, or equivalent or superior** to any currently available treatment or other drugs, biologics or devices.
 - **Promise a certainty of cure** or of other favorable outcomes or benefits beyond what is outlined in the consent and the protocol.
 - **Use terms such as “new treatment,” “new medication” or “new drug”**

- **Promise “free treatment”** when the intent was only to say participants would not be charged for taking part in the study
- Allow for compensation towards the investigational agent once FDA approved
- **Posting Recruitment Materials at Other Sites:** The investigator is responsible for obtaining appropriate prior permission from agencies/institutions at which recruitment materials will be disseminated. Example: Veterans Administration facilities require consultation with the local VA IRB to determine if flyers for non-VA-initiated research may be posted/disseminated.

Screening Activities

Screening procedures may include:

- Any interaction or intervention with the subjects to determine eligibility that would not otherwise have been performed if not for the study, or
- Accessing the results of interventions that were performed for purposes other than the study.

In other words, collecting data directly from subjects or prospective subjects such as through written screening tools or oral responses to questionnaires, or accessing private information, i.e., grades, medical test results, legal records, or any other non-public information linked to a potential subject, for purposes of eligibility screening constitutes a research intervention or interaction that is part of the research activity and therefore requires IRB review.

IMPORTANT NOTE: In order to protect the privacy of potential participants, collect only the minimal information necessary for screening.

All screening procedures are part of the IRB review of proposed research. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures occur because of the research and are, therefore, reviewed by the IRB during consideration of proposed protocols. Screening activities are reviewed as part of the overall recruitment and consent process and evaluated with respect to the protection of privacy and confidentiality of those who are screened.

The webIRB application should include the following information with respect to screening procedures:

- The screening materials which may be used
- Data, if any, that will be acquired
- Whether the investigator intends to retain data from subjects who are ineligible upon screening
- And, if so, why and how the data collected during the screening procedures will be stored.

Additional considerations:

- **Keeping Information Confidential:** Often the greatest risk of obtaining information during the recruitment and/or screening process is the loss of confidentiality. The researcher must consider and describe how the confidentiality of this data will be maintained. Whenever possible, information obtained during this process should not be connected with subject identifiers. As noted above, the amount of data collected should be limited. Once collected it should be kept secure.
- **Developing a screening script for research** may be needed for the oral informed consent process.
 - If such screening activities will take place **prior to the prospective participant providing informed consent** for participation in the research, the researcher may request a waiver of informed consent or signed informed consent for screening activities. See OHRPP Guidance [Requesting Waivers and Exceptions to Informed Consent](#).

- If screening activities will take place only **after the subject has provided informed consent** for participation in the research, then the waivers described above are unnecessary.
- **HIPAA regulations apply to the screening process if it involves review of medical records.** Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent. Please see [OHRPP Guidance & Procedures: HIPAA](#) for details.
- **Telephone Scripts:** In telephone surveys, the initial recruitment call sometimes leads directly into the consent process. In such studies, the script should include, at least, the names of the persons responsible for the study, reference to UCLA, a description of the types of questions that will be asked, an estimate of the time it will take to complete the interview, and the direct question of whether or not a person wishes to participate. The interviewers also should have available an investigator's telephone number in case the prospective subjects have questions about the study that the interviewer cannot answer, and the IRB phone number if there are questions about a research subject's rights.
- **Keeping Information about Refusers:** In general, no identifiable information may be kept about prospective subjects unless they consent to even this limited participation in the research. Describe how this consent will be obtained in webIRB. With IRB approval, non-personally identifying information about refusers may be collected.

If the research cannot be done if refusers' consent to record basic information is required, the IRB will consider waiving consent and that request to waive consent will need to be described in the webIRB application. If, however, screening activities will take place only after the subject has provided informed consent for participation in the research, then the waivers described above are unnecessary.

- **Grouping Questions** for screening purposes, that is, for example, asking subjects a series of five questions that require them to answer the entire group with "yes" or "no" is not a typical or required process. Rather, in most cases the best way to protect confidentiality is to ask only limited information and then to keep that information secure. However, this grouping is sometimes helpful in order to help protect the privacy of the prospective participant and/or to prevent embarrassment.

Regulations and References

DHHS Regulations and References:

- [45 CFR 46.111](#)
- [45 CFR 46.116](#)
- [45 CFR 46.117](#)
- [OHRP, Guidance on Institutional Review Board Review of Clinical Trial Websites](#), September 20, 2005.

FDA Regulations and References:

- [21 CFR 50.20](#)
- [21 CFR 56.111](#)
- [FDA, IRB Information Sheets: Recruiting Study Subjects](#), April 2009 update.
- [FDA, IRB Information Sheets: Screening Tests Prior to Study Enrollment](#), April 2009 Update.

[The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#), April 18, 1979.